DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N–0286]

Withdrawal of Six Guidances on the Clinical Evaluation or Requirements for Approval of Certain Classes of Drugs

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; withdrawal.

SUMMARY: The Food and Drug Administration (FDA) is announcing the withdrawal of six guidances on the clinical evaluation or the requirements for approval of radiopharmaceuticals, antacids, antidiarrheals, laxatives, gastric secretory depressants, and drugs to treat superficial bladder cancer. The guidances are being withdrawn because they are out of date and of little use to the drug industry. The agency has developed other guidances and/or resources to assist the industry in obtaining information on the clinical evaluation and the requirements for approval of these classes of drugs.

DATES: General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to agency guidance documents.

FOR FURTHER INFORMATION CONTACT: Maria R. Walsh, Center for Drug Evaluation and Research (HFD–103), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3139.

SUPPLEMENTARY INFORMATION:

I. Withdrawal of Guidances

FDA is announcing the withdrawal of the following six guidances because they are out of date.

1. Clinical Evaluation of Antidiarrheal Drugs—September 1977

2. Clinical Evaluation of Gastric Secretory Depressant (GSD) Drugs—September 1977

3. Clinical Evaluation of Antacid Drugs—April 1978

4. Clinical Evaluation of Laxative Drugs—April 1978

For information on the topics addressed by the preceding four guidances, contact the Division of Gastrointestinal and Coagulation Drug Products (HFD–180) in the Center for Drug Evaluation and Research (CDER).

5. Clinical Evaluation of Radiopharmaceutical Drugs—October 1981

In the **Federal Register** of June 22, 2004 (69 FR 34683), the agency announced the availability of three guidances for industry on ''Developing Medical Imaging Drug and Biological Products.'' For additional information on developing therapeutic radiopharmaceuticals, contact the Division of Medical Imaging and Radiopharmaceutical Drug Products (HFD–160), CDER.

6. FDA Requirements for Approval for Drugs to Treat Superficial Bladder Cancer—June 1989

For information on the topic addressed by the preceding guidance, contact the Division of Reproductive and Urologic Drug Products (HFD–580), CDER.

II. Comments

Interested persons may submit written or electronic comments to the Division of Dockets Management (see **ADDRESSES**). Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain CDER guidance documents at *http://www.fda.gov/cder/guidance/index.htm*.

Dated: July 13, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–????? Filed ??–??–04; 8:45 am]

BILLING CODE 4160–01–S